DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Mr. Robert Bickford
COO
Paladin Biomedical Corporation
506 Boston Post Road
Weston, Massachusetts 02493

JAN 1 0 2017

Re: K073363
Trade/Device Name: ThermoStat 900 Administration Set, Models ASH200 and ASH300
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LGZ
Dated: March 10, 2008
Received: March 13, 2008

Dear Mr. Bickford:

This letter corrects our substantially equivalent letter of March 20, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Paladin Biomedical Corporation ThermoStat 900 Administration Set

Indications For Use:

Paladin Biomedical Corporation ThermoStat 900 Administration Set is intended to be used with the MMS Thermostat 900 Blood and Fluid Warmer. The disposable cartridge and administration set is intended to deliver high volume, rapid administration of blood and physiological fluids when connected to a large bore catheter. The set is intended to help prevent hypothermia in patients receiving large volumes of fluids.

Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073363

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510K Summary of Safety and Effectiveness
Paladin Biomedical Corporation
ThermoStat 900 Administration Set
Models ASH 200 and ASH 300
506 Boston Post Road
Weston, MA 02493
March 18, 2008

1. Sponsor Name
   Paladin Biomedical Corporation
   506 Boston Post Road
   Weston, MA 02493

2. Device Name
   Proprietary Name: ThermoStat 900 Administration Set
   Common/Usual Name: warmer, thermal, infusion fluid

3. Identification of Predicate or Legally Marketed Device
   BK970045 Microwave Medical System, 310-312 School St., Acton, MA 01720
   Trade Name: ThermoStat 900 Blood & IV Fluid Adm. Set
   Cleared Date: 06-MAR-1998

4. Device Description
   There are two configurations of the administration set the ASH200 (High flow – 2 spike) and ASH300 (high flow – 3 spike). Materials of construction are all known biocompatible materials. The set consists of three major sub assemblies:
   - tubing and administration set consisting of tubing, spikes, clamps, luers, drip chambers
   - filter/vent assembly
   - cartridge assembly.

5. Intended Use
   Paladin Biomedical Corporation ThermoStat 900 Administration Set is intended to be used with the MMS Thermostat 900 Blood and Fluid Warmer. The disposable cartridge and administration set is intended to deliver high volume, rapid administration of blood and physiological fluids when connected to a large bore catheter. The set is intended to help prevent hypothermia in patients receiving large volumes of fluids.

6. Comparison of Technological Characteristics
   The Paladin Biomedical Administration Set and the MMS Administration Sets were compared with respect to various attributes (Dimensions, warming method, filter size, flow rate, and maximum pressure) and determined to be the same with respect to materials, design, specifications, construction, and performance.

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7 Performance Testing

Bench testing was performed to determine equivalency and performance aspects of the device.

8. Statement of Equivalency

The Paladin System is substantially equivalent in design, materials, construction and intended use as that of the predicate. Since the Paladin device is the same in intended use and technological characteristics as the predicate device, the Paladin device does not raise any new safety and efficacy concerns when compared to these similar legally marketed devices.

The descriptive characteristics demonstrate that the Paladin device is substantially equivalent to the predicate device and is capable of safely and accurately performing the stated intended use.